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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,232	08/26/2003	Edward P. Ingenito	ATX-011.04	6203

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EXAMINER	
VU, QUYNH-NHU HOANG	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/649,232	INGENITO, EDWARD P.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/1/08 & 8/29/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13, 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 8/29/08 has been entered.

Claims 1-13, 15-18 are present for examination.

Claim 14 is cancelled.

Terminal Disclaimer

An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 15-18 are rejected under 35 U.S.C. 103(a) as obvious over Perkins et al. (US 6,287,290).

Perkins discloses an optional methods, systems and kits for lung volume reduction that includes advancing the bronchoscope (see 2: 15+ and 8:18+) and introducing composition or biological material comprising a sealing (introducing fibrin glue, see col. 10:35+) or occluding a plug 282 containing anti-surfactant (collagen hydrogel) to collapse the diseased alveolar (CLT) region (see 10: 37+). The collapsed region will be sealed by methods include the use of suturing, gluing energy mediated tissue adhesion etc…, such as tissue adhesive, such as fibrin glues (2, 35+) or using a plug of hydrated collagen hydrogel (biological material for promoting fibrosis and increasing surface tension).

Thus, it would have been obvious to a person of ordinary skill in the art to try the sealing or occluding plug method in an attempt to collapsed tissue region, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp. In turn, the method of sealing or occluding plug as suggested in the prior art, it would have been obvious to use for collapsing or lung volume reduction.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins in view of Edwardson et al. (US 5,739,288).

Perkins meets the claim limitations as described above but fails to disclose the use of fibrinogen and a fibrinogen activator such as thrombin.

Edwardson discloses a fibrin sealant composition that can be used for sealing tracheal and bronchial anastomoses and air leaks or lacerations of the lung (promoting fibrosis) that includes fibrinogen, thrombin, clot promoting factor XIIIa and antibiotics. Since the invention of Perkins is drawn to closing a region of the lung by gluing tissue (see Perkins 10:40) and Edwardson teaches a composition to enhance the closure of leaks or laceration of the lung (i.e. a tissue sealant) a combination is proper. At the time of the invention, it would have been obvious to use the fibrin sealant of Edwardson et al. in order to provide an enhanced fibrin formulation for tissue closure thereby improving patient recovery time.

Applicant also admitted that the activators are known in the art and include thrombin (page 7, lines 23+ of Specification).

Claims 2-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins in view of Edwardson and further in view of Antanavich et al. (US 5,814,022).

Perkins meets the claim limitations as described above but fails to include the composition comprising 3-12% fibrinogen.

Edwardson discloses a fibrin sealant composition that can be used for sealing tracheal and bronchial anastomoses and air leaks or lacerations of the lung (promoting fibrosis) that includes fibrinogen, thrombin, clot promoting factor XIIIa and antibiotics. Since the invention of Perkins is drawn to

closing a region of the lung by gluing tissue (see Perkins 10:40) and Edwardson teaches a composition to enhance the closure of leaks or laceration of the lung (i.e. a tissue sealant) a combination is proper. At the time of the invention, it would have been obvious to use the fibrin sealant of Edwardson in order to provide an enhanced fibrin formulation for tissue closure thereby improving patient recovery time.

Perkins in view of Edwardson meets the claim limitations as described above but fails to include the composition comprising 3-12% of fibrinogen.

Antanavich discloses a method and apparatus for applying tissue sealant that includes that use of an adhesive protein solution having a fibrinogen content of from 3 to 12% with clot promoting factor XIIIa and further notes that one reason for this arrangement is that the strength of the sealant is proportional to the fibrinogen concentration. Since the invention of Perkins is drawn to closing a region of the lung by gluing tissue (see Perkins 10: 40) and Antanavich teaches an enhanced fibrin sealant composition a combination is proper. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to incorporate the concentration of fibrinogen as taught by Antanavich into the invention of Perkins in order to have an adhesive protein solution that is less prone to clogging before administered to the therapeutic site as taught by Antanavich. Furthermore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the composition of fibrinogen from 3-12%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 15, 22, 23, 31, 55, 60 of copending Application No. 10/069307; claims 1-18 of copending Application No. 10/649,232; claims 1-11 of US Patent No. 6,610,043; claims 1-32 of US Patent No. 6,682,520; claims 1-4 of US Patent No. 7,300,428.

Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are fully disclosed and covered by the claims of the copending application claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 08/28/07 have been fully considered but they are not persuasive.

1. Applicant argues on pg 2 of 5 on Remark filed 8/29/08 that:

> Perkins teaches ***optionally*** sealing or occluding an air passage leading to the collapsed region of the lung by "delivering a plug…, typically as [*sic*] partially hydrated collagen hydrogel…" ***after*** the lung has been collapsed by vacuum aspiration or the application of external force. (See column 9, lines 24-29; column 10, lines 37-58; and Figure 4C)
>
> In contrast, the Applicant's claimed methods relate to reducing lung volume by administering a composition comprising an anti-surfactant to a diseased alveolar region of the lung where administering the composition promotes collapse and sealing of the diseased alveolar

In response, although Perkins suggest the methods of his inventions will optionally comprise sealing or occluding the air passage to collapsed tissue region CLT (col. 10, lines 35+). Thus, one skill in the art would try to use a known method such as the sealing or occluding plug by introducing the anti-surfactant (hydrated collagen hydrogel or fibrin glue) to collapsed the lung tissue region.

2. Applicant argues that Perkin does not teach or suggest administering the anti-surfactant in to a diseased alveolar region of the patient's lung to promote collapse.

In response, as discussed above, Perkins suggests one of the methods to collapse tissue region (diseased alveolar region) is sealing or occluding the plug. Perkins clearly discloses that introducing plug 282 containing/including a hydrated collagen hydrogel (anti-surfactant) into lung area to promote collapse (Fig. 11, col. 10, lines 35+).

Perkins discloses that air passage may be sealed or occluded with fibrin glues (col. 2, lines 33-40, col. 10, lines 37-42). In order to seal with fibrin glue, the method must be introduce the anti-surfactant (adhesive or sealant materials such as fibrin) into alveolar region (diseased region) for sealant/adhering the tissue.

3. Response to the argument of claims 2-13 under 35 U.S.C. 103 rejections.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763